



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,253	08/29/2001	Joseph F. Poduslo	07039-351001	6205

26191 7590 09/09/2003

FISH & RICHARDSON P.C.
3300 DAIN RAUSCHER PLAZA
60 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT PAPER NUMBER

1646

DATE MAILED: 09/09/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/942,253

Applicant(s)

PODUSLO ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 10-15 and 18-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in Paper No. 6 is acknowledged.

Claims 10-15 and 18-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Claims 1-9 and 16-17 are under examination in the instant office action.

Specification

2. The use of the trademarks has been noted in this application, see page 9, line 6 and page 11, line 13, for example. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Objections

3. Claims 4-6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Art Unit: 1646

Claims 4-6 are directed to a composition comprising A β polypeptide linked to an antibody comprising different antibody fragments. Due to the use of "comprising language", claims 4-6 cover the same subject matter as claim 3, from which they depend and which is directed to a composition comprising A β polypeptide linked to an antibody comprising all the different fragments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 1 recites the limitation "an amyloid β (A β) polypeptide" followed by the recitation "said A β polypeptide". There is insufficient antecedent basis for the limitation "A β polypeptide" in the claim. Applicant is advised that recitation of "A β (amyloid β) polypeptide" or "A β polypeptide" at first appearance of the limitation in the claim would obviate this ground of rejection.
6. Claim 7 is vague and indefinite for recitation of an antibody that "has specific binding affinity", emphasis added. The metes and bounds of the recitation cannot be determined from the claim or the instant specification because it is not clear if the specificity is defined by binding to a specific epitope, or to a protein from a particular species, or both.
7. Claims 2-6, 8, 9, 16 and 17 are indefinite for being dependent from indefinite claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito et al., 1995 (PNAS, Vol.92, pp.10227-10231).

Claims 1-6, 16 and 17 are directed to a composition comprising A β polypeptide linked to a non-A β polypeptide. Saito et al. describe a composition comprising A β^{1-40} polypeptide linked to the OX26 monoclonal antibody to the rat transferring receptor (see abstract and section Material and Methods on page 10227). This composition comprised a pharmaceutically acceptable carrier because it was used in the intravenous injection (page 10228, Intravenous Injection Technique). Furthermore, the monoclonal antibody of Saito et al. comprises all the fragments recited in claims 4-6, absent evidence to the contrary. Thus, publication of Saito et al. anticipates claims 1-6 and 16-17 of the instant invention.

9. Claims 1 and 3-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Majocha et al. (US Patent 5,231,000, reference AA of the IDS of Paper No. 4).

Claims 1, 3 and 7 are directed to a composition comprising A β polypeptide linked to non-A β polypeptide, wherein said non-A β polypeptide is an antibody with specific binding affinity for amyloid. Majocha et al. disclose antibodies to amyloid polypeptide (A4 amyloid, which corresponds to A β polypeptide, residues 1-26, see Figure 1 of the Majocha et al. document and

Art Unit: 1646

compare to the SEQ ID NO: 1 of the instant invention). Antibodies of Majocha et al. were used to immunostain amyloid in AD brain section (column 9, lines 43-64) as well as parenchymal deposits of amyloid (column 10, 12-15). Thus, Majocha et al. disclose a composition comprising A β polypeptide, a constituent of amyloid plaques, linked to an antibody with specific affinity to amyloid. Because A β polypeptide of the instant invention encompasses "naturally occurring human A β polypeptide" (see page 4, lines 9-10 of the instant specification), disclosure of Majocha et al. meets the limitations of claims 1, 3 and 7. Document of Majocha et al. further anticipates claims 4-6 because the antibodies disclosed therein comprise all the fragments recited in claims 4-6. Furthermore, antibodies used in Majocha et al. document were labeled with a detectable label, such as a radioisotope or "other suitable labels for binding to the antibodies" (column 3, lines 55-68 going to column 4, lines 1-17), which encompasses a contrast agent, for example. Therefore, Majocha et al. anticipate claims 8-9 of the instant invention.

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 1646

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-7939. Official papers should NOT be faxed to (703) 308-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.

